

REMARKS

Claims 1-34 are in the case. Claims 1, 2, 16, 25, 27 and 28 have been amended. No new matter has been introduced. Claims 1, 2 and 16 have been amended to include the subject matter of claim 7, and claims 25, 27 and 28 have been amended to correct an error in antecedence. Claim 7 has been cancelled without prejudice.

Claims 1-7, 9-13 and 15-34 have been rejected under 35 USC §102(e) as being anticipated by the newly-cited Lennon et al reference. Claims 8 and 14 have been rejected under 35 USC §103(a) as being unpatentable over the Lennon et al. reference, in view of Chandler (U.S. Patent 6,165,416).

Applicants respectfully submit that claims 1, 2 and 16, as amended, are not anticipated by Lennon. To anticipate a claim, a reference must disclose every element of the claim. Each of Applicants' independent claims requires that the housing include a first aperture communicating with the internal recess, and an additional aperture which is separate from the first aperture and which also communicates with the internal recess. Providing these two separate apertures allows the housing to receive at least a portion of the sample collection device into the internal recess through the first aperture and an insertable testing element that is separate from said sample collection device through the additional aperture. Because the sample collected on the sample collection device is shielded within the internal recess, the sample can be tested at a later time and/or in a different place by inversion of the testing element into the housing through the additional aperture. (See Applicants' Specification, page 6, lines 19-25.)

Lennon et al. does not disclose devices that include two separate apertures as recited in Applicants' claims. Instead, it appears that in the Lennon devices the sample swab is generally placed in the first receptacle 20, defined by panel 18, prior to bringing the first and second opposable components 12, 14 into operable contact to define a housing. Thus, the sample is not inserted through an aperture, but rather is simply placed on what would be the back side of panel 18 in Fig. 1 of Lennon. Before or after the components 12, 14 are brought into contact, the test strip is inserted into a second receptacle 22 that is defined by panels 16 and 18. Where or how the test strip is inserted, in the case in which it is later inserted, is not clearly described.

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Serial No. : 09/936,452
Filed : September 12, 2001
Page : 9 of 9

Attorney's Docket No.: 13521-
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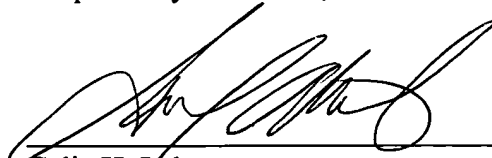
Applicants' claimed devices are suitable for use in situations where the sample to be tested is collected at a site that lacks laboratory facilities, equipment, and highly trained or skilled personnel, e.g., in a patient's home or in a rural area. The claimed devices are also suitable for manufacture by established high-speed processes and technologies (see page 8, lines 4-24). Because Applicants' claimed devices include a housing defining two apertures, rather than the opposable components or panels employed in the cited Lennon et al. devices, the claimed devices are simple and economic to manufacture and to use, and are particularly suitable for use in situations where the testing function is not linked to the collection of a sample (see Applicants' specification, page 4, lines 17-20 and page 6, lines 19-25).

The Chandler reference, cited to provide a teaching of guaiac-based test strips, does not supply that which is lacking in the primary reference. Accordingly, Applicants respectfully submit that the claims are patentable over the combination of Lennon and Chandler for the reasons discussed above and respectfully request that the rejection under 35 U.S.C. §103 be withdrawn.

Enclosed is a \$55 check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No. 13521-002001.

Respectfully submitted,

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